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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,252	GUIMBERTEAU ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/07/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/03/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of list of claims and Applicant's remarks dated 12/7/2009 is acknowledged.

The rejections that are not reiterated in the current office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 19-26 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 as amended recites that "the coating film is between about 3% and about 7%". The instant specification does not support this recitation. While the specification recites at least 3%, preferably at least 5% and most preferred a range of 3 and 40% dry weight/dry weight. There is no support for the recitation of the range recited of about 3%, to about 7%. In accordance with MPEP 714.02 applicants should specifically point out support for the generic concept of claim 1 using the range "the coating film between about 3% and about 7%".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 17, 19-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Autant et al. US 6022562 (Autant), the reference has been provided by Applicant in the Information Disclosure Statement dated 02/03/2010.

Autant teaches microcapsules for the oral administration of medicinal and/or nutritional active principles (AP), which are smaller than or equal to 1000 micron in size. The microcapsules consist of particles of the active principle which are coated with a coating material (corresponds to the core and coating of the instant claims) consisting of a mixture of a film-forming polymer derivative, a hydrophobic plasticizer, a functional agent and a nitrogen-containing polymer (abstract). The coating film of specific following composition:

1- at least one film-forming polymer (PI) which is insoluble in the liquids of the digestive tract, present in a quantity of 50 to 90%, preferably 50 to 80% by weight of dry matter of the whole coating composition, and consisting of at least one non-hydrosoluble cellulose derivate, ethylcellulose and/or cellulose acetate being preferred.

2- at least one nitrogen-containing polymer (P2), present in a quantity of 2 to 25, preferably 5 to 15% by weight of dry matter of the whole coating composition, and consisting of at least one polyacrylamide and/or one poly-N-vinylaride and/or one poly-N-vinyl-lactame, the polyacrylamide and/or the polyvinylpyrrolidone being preferred.

3- at least one plasticizer present in a quantity of 2 to 20%, preferably 4 to 15% by weight of dry matter of the whole coating composition, and consisting of at least one of the following compounds :glycerol esters, phtalates, citrates, sebacates, cetylalcohol esters, castor oil and cutin, castor oil being particularly preferred;

4- at least one surface-active and/or lubricating agent, present in a quantity of 2 to 20%, preferably 4 to 15% by weight of dry matter of the whole coating composition, and chosen from anionic surfactants, preferably the alkali metal or alkaline-earth metal salts of fatty acids, stearic acid and/or oleic acid being preferred, and/or from nonionic surfactants, preferably polyoxyethylenated esters of sorbitan and/or polyoxyethylenated esters of sorbitan and/or polyoxyethylenated derivatives of castor oil, and/or from lubricants such as stearates, preferably calcium, magnesium, aluminium or zinc stearate, or such as stearylfumarate, preferably sodium stearylfumarate, and/or glyceryl behenate, said agent comprising only one or a mixture of the above products (col. 6, lines 61 bridging to col. 7, lines 1+).

The amount of coating agent in the microcapsules represents from 5 to 40% of the weight of the coated microcapsules (col. 11, lines 59-61).

The particles of active principle, of desired particle size and necessary for the production of microcapsules according to the invention, may be undergone granulation in the presence of a small amount of at least one standard binder and/or of an agent modifying the intrinsic solubility feature of the ACTIVE PRINCIPLE (col. 11, lines 47+). The solubility modifying agent can be PVP (example 3).

Thus, since the microcapsule disclosed by Autant anticipated the microcapsule recited in the instant claims, then the functional properties required by the instant claims such as increasing the solubility of the active principle by 50%, the release, and dissolution of the active principle are inherent properties because same compositions have the same properties. In addition, the mass fraction required by instant claims 17 and 19 are expected to be the same mass fraction of Autant's microcapsule because Autant discloses amounts that are the same, encompassed or overlapping with the amounts recited in the instant claims.

The active principle can be antiulcer, antidiabetic, anticoagulant, antithrombic, hypolipaemic, antiarrhythmic, vasodilator, antianginal, antihypertensive, and vasoprotective agents, fertility enhancers, labor inducers and inhibitors, and contraceptive, antibiotic, antifungal, antiviral, anticancer, anti-inflammatory, analgesic, antiepileptic, antiparkinsonian, neuroleptic, hypnotic, anxiolytic, psychostimulatory, antimigraine, antidepressant, antitussive, antihistamine or anti-allergic agents. Preferably, chosen from prazosin, acyclovir, nifedipin, diltiazem, naproxen, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, diclofenac, etc. (col. 10, lines 42+).

Regarding claims 29-32 which recite a medicinal product containing the microcapsule recited in the claims. The same microcapsule was disclosed by Autant as shown supra in addition to disclosing the galenical systems such as tablets, powders, gelatin capsules, (col. 12, lines 20+). Further, Autant's disclosure makes it possible to ensure the sustained release of the active principle used (col. 7, lines 46+) and ensure that the system to reside in the small intestine for a period which is considerably longer

than the time of natural transit (col. 6, lines 7+). Also the lubricant surfactant (TA) required by instant claim 32 is inherent to the amount of (TA) used and which is the same as disclosed by Autant (4-15%).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-17 and 19-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Autant et al. US 6022562 (Autant).

The claims are alternatively rejected as obvious over Autant et al. as follows:

Autant is relied upon for the reasons set forth hereinabove.

Autant did not specify the active principle as a low soluble AP. The reference teaches that the invention suits a large number of active principles having solubilities of between a few milligrams and a few hundred grams per liter (col. 8, lines 32+).

It would have been obvious to a person having ordinary skill in the art at the time the instant invention was made to make the microcapsule containing a low solubility active principle because Autant teaches that the disclosed particles of AP may have been undergone a pretreatment by one of the conventional techniques of the art such as, for example, granulation in the presence of a small amount of an agent modifying the intrinsic solubility feature of the AP. The person of ordinary skill in the art would be motivated by Autant's disclosure that the coating film is advantageously of sufficient mechanical strength to prevent it breaking and/or splitting in the body, the microcapsule

have a high content of the AP between 55 and 95% by weight, and even in the case of prolonged adhesion to the gastrointestinal mucous membranes, the microcapsule has no risk of ulceration. The artisan would expect excellent results of having a low soluble active principle in a core coated by a coating that delays and sustains the release of the AP in a microcapsule that is included in a tablet, a gelatin capsule or powder.

Response to Arguments

Applicant's arguments with respect to claims 16-17 and 19-32 have been considered but are moot in view of the new ground(s) of rejection.

The exhibits provided by Applicant as evidence for the difference between vinyl pyrrolidone and polyvinylpyrrolidone have been considered but are not considered relative to the current office action.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 02/03/2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618